VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

November 19, 2019

COPN Request No. VA-8429

Roanoke Valley Center for Sight, LLC
Roanoke, Virginia

Expand scope of surgery services for one ophthalmic operating room to permit ENT surgery at their Roanoke City facility

Applicant

Roanoke Valley Center for Sight, LLC (RVCS) is a proprietary Virginia limited liability company originally incorporated as the Southwest Virginia Ambulatory Surgery Center, LLC and amended in November 2000 to RVCS. RVCS currently has eighteen members, each of whom own 5.56% of the company. RVCS is located in Planning District ("PD") 5, Health Planning Region ("HPR") III.

Background

In 2001, the State Health Commissioner (Commissioner) issued COPN No. VA-03510, which authorized RVCS to establish an outpatient surgical hospital ("OSH") with one operating room ("OR") limited to the provision of ophthalmic surgery in Salem, Virginia. In 2004, the Commissioner issued COPN No. VA-03737, which authorized RVCS to add a second OR, limited to the provision of ophthalmic surgery, at their existing OSH in Salem, Virginia. In 2014, the Commissioner issued COPN No. VA-04449, which authorized RVCS to establish a second OSH with one OR limited to the provision of ophthalmic surgery in Roanoke, Virginia. In 2017, the Commissioner issued COPN No. VA-04585, which authorized RVCS to establish a third OSH with one OR limited to the provision of ophthalmic surgery in Martinsville, Virginia. In 2018, the Commissioner issued COPN No. VA-04635, which authorized RVCS to establish a fourth OSH with one OR limited to the provision of ophthalmic surgery in Wytheville, Virginia.

Proposed Project

There are currently eight authorized surgery programs in PD 5. Collectively, there are 64 certificate of public need (COPN) recognized general-purpose operating rooms (GPOR) located

in PD 5. As of 2017, there were 60 operational GPORs in PD 5, 50 of which were located in acute care hospitals, with the remaining ten located in outpatient surgical hospitals (Table 1). RVCS proposes to expand the use of their limited use ophthalmic OR located at their Roanoke facility to include otorhinolaryngologic surgery, which is a surgical subspecialty within medicine that deals with conditions of the ear, nose, and throat (ENT). The total capital cost of this proposed project is estimated to be \$25,620 (Table 2) and would be funded entirely through the internal resources of RVCS.

Table 1: General Purpose Operating Rooms in PD 5

Acute Care Hospital	Operating Rooms
Carilion Roanoke Community Hospital ¹	7
Carilion Roanoke Memorial Hospital	28
LewisGale Hospital - Alleghany	5
LewisGale Medical Center	14
TOTAL	54
Outpatient Surgical Hospital	
Blue Ridge Surgery Center	4
Fairlawn Surgery Center, LLC	1
Roanoke Ambulatory Surgical Center	3
Roanoke Valley Center for Sight	2
TOTAL	10
Grand Total	64

Source: VHI and COPN data

Table 2. Capital and Financing Costs

Equipment	\$25,620
TOTAL Capital and Financing Costs	\$25,620

Source: COPN Request 8429

Project Definition

Section 32.1-102.1 of the Code of Virginia defines a project, in part, as the "increase in the total number of beds or operating rooms in an existing medical care facility". While no numeric increase in operating room (OR) capacity is proposed, the COPN issued for the subject OR restricted its use to ophthalmic and oculofacial surgery when a 13 OR surplus existed in the PD. Authorizing the expansion of allowable services to include ENT surgery effectively increases the inventory of ORs generally available for other than ophthalmic and oculofacial surgery. A medical care facility is defined, in part, as "Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery..."

¹ On December 17, 2018, the Commissioner issued COPN No. VA-04636 to Carilion Medical Center authorizing the addition of four operating rooms. These operating rooms are expected to become operational on December 1, 2020.

Required Considerations -- § 32.1-102.3, of the Code of Virginia

In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable.

The extent to which the proposed service or facility will provide or increase access to
needed services for residents of the area to be served, and the effects that the proposed
service or facility will have on access to needed services in areas having distinct and
unique geographic, socioeconomic, cultural, transportation, and other barriers to access
to care.

RVCS proposes to expand the scope of the limited use ophthalmic operating room located at their Roanoke location to include ENT surgeries. The ENT specialist who will perform these surgeries, Dr. Lenkowski, currently performs surgery at Blue Ride Surgery Center ("BRSC"). DCOPN received letters of support and public comments relaying experiences with BRSC postponing or rescheduling ENT procedures. Some of these patients must travel upwards of an hour, often very early in the morning, to arrive for their surgical appointments. Members of the public stated that approval of the project would eliminate the possibility of this occurring and avoid potentially prohibitive travel for rescheduled surgical appointments. This argument was not made by RVCS and no evidence was submitted to support this assertion. As such, DCOPN must conclude that these assertions are too speculative to determine that such a transportation barrier to access of care exists.

Geographically, RVCS' Roanoke facility is located less than 200 feet from SR-419, which connects to I-81 approximately 5.6 miles from RVCS. The applicant makes no mention of public transportation accessibility and DCOPN's review of public transit schedules did not show any route that could reasonably be used to access the facility. DCOPN thus concludes that the facility is not reasonably accessible by public transportation.

DCOPN is not aware of any additional geographic, socioeconomic, cultural, or transportation barriers to access to care.

- 2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:
 - (i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served.

DCOPN received 22 letters of support for the proposed project. Collectively, these letters articulated issues that the members of the public had experienced with larger outpatient surgery centers, particularly issues with insurance, billing, and having their surgeries delayed or rescheduled. Additionally, these letters discussed the benefits of the project, specifically citing increased quality of care, flexibility of scheduling, and lessened cost.

DCOPN received one letter of opposition for the proposed project from BRSC. The letter is largely a refutation of a letter received in support of the project from Dr. Lenkowski. In the letter, BRSC asserts that Dr. Lenkowski has additional time at BRSC in which he could perform surgeries. The letter additionally states that Dr. Lenkowski has lauded the quality of BRSC, which is something that was confirmed in Dr. Lenkowski's statements at the public hearing. Moreover, BRSC states Dr. Lenkowski's patients would receive better care at BRSC because they have a historically higher volume of ENT-related surgical cases than would be seen at RVSC should the proposed project receive approval. Finally, BRSC states that the proposed project is inconsistent with public need because convenient high-quality outpatient surgical services are already available at BRSC.

Public Hearing

DCOPN conducted the required public hearing on October 18, 2019. A total of 16 individuals were in attendance. Ten individuals in attendance indicated that they were in support of the proposed project and two individuals indicated that they were opposed to the proposed project. The project was presented by one individual representing RVSC. Five members of the public spoke in support of the proposed project. Collectively, they asserted that the proposed project would provide a lower cost option for residents of PD 5 and provided personal accounts of issues they had experienced with ENT surgeries at BRSC. One individual representing BRSC spoke in opposition of the proposed project. In his public comment, the individual from BRSC reiterated the points raised in their letter of opposition.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner.

BRSC, in their letter of opposition, contends, and DCOPN agrees, that the status quo is a viable alternative to the proposed project. One of the two main points raised in favor of the proposed project by RVCS is that Dr. Lenkowski performing ENT surgeries at RVCS would be a more convenient option for his patients. As BRSC is located 1.4 miles away from RVSC, DCOPN finds it unlikely that approval of the project would increase access to ENT care for residents of PD 5.

RVCS also states that there is an unmet need in the planning district for an outpatient facility dedicated to ENT and related facial surgery. RVCS does not provide any information in support of this assertion nor do they indicate how approval of the proposed project would transform their Roanoke location into such a facility. As such, DCOPN must conclude that the assertion by RVCS is too speculative to rely on, particularly in light of the evidence presented by BRSC in their letter of opposition.

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6.

Not applicable. Currently there is no organization in HPR III designated by the Virginia Department of Health to serve as the regional health-planning agency for the southwestern Virginia region.

(iv) Any costs and benefits of the project.

As demonstrated by Table 2, the total capital cost of this proposed project is estimated to be \$25,620, and would be funded through the internal resources of RVCS. The costs of this project, which are limited solely to additional equipment to be added to the ophthalmic operating room that are necessary to perform ENT surgery, are minimal and reasonable. While the project is inexpensive, the applicant does not raise any benefits to the project outside of those previously discussed unsupported claims that DCOPN finds too speculative to adopt.

(v) The financial accessibility of the project to the residents of the area to be served, including indigent residents.

In their application, RVCS asserts that they have saved residents of PD 5 more than 80 million dollars compared to hospital based alternatives. In 2017, the last year for which VHI has information available, RVCS provided 1.6% of its gross patient revenue in the form of charity care, which is well below the 3% regional average for HPR III. Accordingly, should the State Health Commissioner approve the proposed project, RVCS is expected to provide a level of charity care for total gross patient revenues that is no less than the equivalent average for charity care contributions in HPR III.

Table 3: HPR III 2017 Charity Care Contributions

Health Pla	nning Region III		Charles (196
2017 Charity Care Contributions a	t or below 200% of	Federal Poverty Lev	el a
Hospital	Gross Patient Revenues	Adjusted Charity Care Contribution	Percent of Gross Patient Revenue:
Carilion Franklin Memorial Hospital	\$132,460,528	\$13,221,787	9.98%
Carilion Tazewell Community Hospital	\$51,270,952	\$3,545,397	6.92%
Carilion New River Valley Medical Center	\$575,422,228	\$34,537,492	6.0%
Bedford Memorial Hospital	\$90,839,221	\$4,601,640	5.07%
Dickenson Community Hospital	\$21,792,258	\$1,091,312	5.01%
Carilion Giles Memorial Hospital	\$91,718,230	\$4,416,694	4.82%
Russell County Medical Center	\$106,260,108	\$4,945,916	4.65%
Wellmont Lonesome Pine Mt. View Hospital	\$347,713,955	\$15,068,909	4.33%
Carilion Medical Center	\$3,304,532,400	\$141,721,067	4.29%
Norton Community Hospital	\$266,517,896	\$10,635,552	3.99%
Smyth County Community Hospital	\$170,503,003	\$6,286,906	3.69%
Johnston Memorial Hospital	\$818,991,727	\$26,059,815	3.18%
Centra Health	\$1,881,573,155	\$56,858,507	3.02%
Twin County Regional Hospital	\$217,008,612	\$4,235,172	1.95%
Lewis-Gale Medical Center	\$1,707,793,744	\$29,362,626	1.72%
Pulaski Community Hospital	\$273,123,208	\$4,648,169	1.70%
LewisGale Hospital Montgomery	\$507,547,975	\$7,573,082	1.49%
Buchanan General Hospital	\$101,076,839	\$1,241,886	1.23%
LewisGale Hospital Alleghany	\$190,699,378	\$2,095,426	1.10%
Clinch Valley Medical Center	\$457,466,111	\$3,619,982	0.79%
Danville Regional Medical Center	\$738,517,420	\$4,340,138	0.59%
Wythe County Community Hospital	\$240,309,812	\$1,202,861	0.50%
Memorial Hospital of Martinsville & Henry County	\$546,148,162	\$1,537,981	0.28%
Total \$ & Mean %	\$12,839,286,922	\$382,848,317	3.0%

Source: 2017 VHI Data

(vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project.

On September 9, 2014 the Commissioner issued COPN number VA-04449 authorizing the establishment of Roanoke Valley Center for Sight – Roanoke as a 1 OR outpatient surgical hospital limited to ophthalmic surgery. In approving COPN number VA-04449 the Commissioner cited as reasons, among others, that;

1. "The proposed project to add one outpatient operating room dedicated to ophthalmic and oculofacial plastic surgery through the establishment of an outpatient surgical hospital is generally consistent with the <u>State Medical Facilities Plan</u> and the 8 Required Considerations of the <u>Code of Virginia</u>.

2. The applicant has demonstrated an institutional specific need to increase its surgical capacity to meet existing and projected surgical demand by residents of the Roanoke Metropolitan Statistical area and surrounding area, but is unable to do so at its existing facility."

In demonstrating a need for the new outpatient surgical hospital the applicant demonstrated a case for public need based on the need for eye surgery capacity, despite an SMFP calculated excess of 13 ORs in the planning district.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

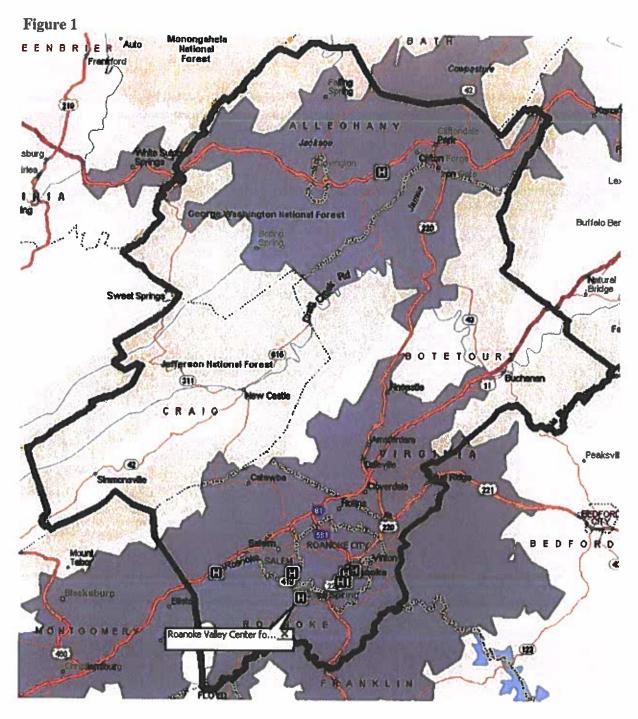
The State Medical Facilities Plan (<u>SMFP</u>) contains criteria/standards for the addition of general-purpose operating rooms and the addition of cardiac catheterization equipment. They are as follows:

Part V General Surgical Services Criteria and Standards for General Surgical Services

12VAC5-230-490. Travel Time.

Surgical services should be available within 30 minutes driving time one way under normal conditions for 95% of the population of the health planning district using mapping software as determined by the commissioner.

The black line in Figure 1 identifies the boundary of PD 5. The dark "H" signs in Figure 1 mark the locations of the COPN approved GPORs in PD 5. The shading illustrates the area that is within a 30-minute drive time in normal driving conditions of a COPN approved GPORs. As the proposed location already offers limited surgical services in the form of ophthalmic surgery and is less than two miles from BRSC, where ENT surgery is currently performed, the proposed project is highly unlikely to improve geographic access to surgical services for residents of PD 5.



12VAC5-230-500. Need for New Service.

A. The combined number of inpatient and outpatient general purpose surgical operating rooms needed in a health planning district, exclusive of procedure rooms, dedicated cesarean section rooms, operating rooms designated exclusively for cardiac surgery, procedures rooms or VDH-designated trauma services, shall be determined as follows:

FOR = ((ORV/POP) x (PROPOP)) x AHORV 1600

Where:

ORV = the sum of total inpatient and outpatient general purpose operating room visits in the health planning district in the most recent five years for which general purpose operating room utilization data has been reported by VHI; and

POP = the sum of total population in the health planning district as reported by a demographic entity as determined by the commissioner, for the same five-year period as used in determining OPV

as used in determining ORV.

PROPOP = the projected population of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

AHORV = the average hours per general purpose operating room visit in the health planning district for the most recent year for which average hours per general purpose operating room visits have been calculated as reported by VHI.

FOR = future general purpose operating rooms needed in the health planning district five years from the current year.

1600 = available service hours per operating room per year based on 80% utilization of an operating room available 40 hours per week, 50 weeks per year.

The preceding formula can be used to affirm whether there is currently an excess of GPORs in PD 5. The preceding formula can also determine the overall need for operating rooms within PD 5 five years from the current year, i.e., in the year 2024. The current GPOR inventory for PD 5 is broken down by facility, category, and utilization rate as shown in Table 4.

Table 4: COPN Authorized GPOR Inventory for PD 5: 2017

Acute Care Hospital	Operating Rooms	Total Hours	Use Per OR	Utilization Rate
Carilion Roanoke Community Hospital	3	3,506	1,168.7	73.0%
Carilion Roanoke Memorial Hospital	28	20,470	731.1	45.7%
LewisGale Hospital - Alleghany	5	1,447	289.4	18.1%
LewisGale Medical Center	14	10,421	744.4	46.5%
TOTAL and Average	50	35,844	716.9	44.8%
Outpatient Surgical Hospital				
Blue Ridge Surgery Center	4	3,927	981.8	61.4%
Fairlawn Surgery Center, LLC	ı	2,105	2,105.0	73.0%
Roanoke Ambulatory Surgical Center	3	3,705	1,235.0	45.7%
Roanoke Valley Center for Sight	2	10,511	5,255.5	131.6%
TOTAL and Average	10	20,248	2,024.8	126.6%
Grand Total	60	56,092	934.9	58.4%

Source: 2017 VHI Data

Based on operating room utilization submitted to and compiled by VHI, for the five year period 2013 through 2017, which is the most recent five-year time span for which relevant

data is available, the total numbers of reported inpatient and outpatient operating room visits to hospital-based and freestanding (i.e., to outpatient surgical hospitals/ambulatory surgical centers) are shown in Table 5.

Table 5: Inpatient & Outpatient GPOR Utilization in PD 5: 2013-2017

Year	Total Inpatient & Outpatient Operating Room Visits
2013	51,150
2014	53,755
2015	52,587
2016	52,499
2017	52,165
Total	262,156
Average	52,431

Source: 2013-2017 VHI Data

Based on actual population counts derived as a result of the 2010 U.S. census, and population projections as compiled by Weldon Cooper, Table 6 presents the U.S. Census' baseline population estimates for PD 5 for the five years 2013-2017 as follows:

Table 6: PD 5 Population:

2013-2017 & 2024		
Year	Population	
2013	275,724	
2014	276,151	
2015	276,631	
2016	277,167	
2017	277,759	
Total	1,383,433	
Average	276,687	
2024	281,247	

Source: Weldon Cooper

Note: Straight Line Extrapolation

Based on the above population estimates from the 2010 U.S. Census, and using a straight-line, average annual increase of 533 from 2010 to 2020 and 410 from 2020 to 2030, the cumulative total population of PD 5 for the same historical five-year period as referenced above, 2013-2017, was 1,383,433, while the population of PD 5 in the year 2024 (PROPOP—five years from the current year) is projected to be 281,247. These figures are necessary for the application of the preceding formula, as follows:

ORV ÷	POP =	CSUR
Total PD 5 GPOR Visits 2013 to 2017:	PD 5 Historical Population 2013 to 2017:	Calculated GPOR Use Rate 2013 to 2017:
262,156	1,383,433	0.1895

CSUR *	PROPOP =	PORV
Calculated GPOR Use Rate 2013 to 2017:	PD 5 Projected Population 2024:	Projected GPOR Visits 2024:
0.1895	281,247	53,295

AHORV is the average hours per operating room visit in the planning district for the most recent year for which average hours per operating room visit has been calculated from information collected by the Virginia Department of Health.

AHORV = 100,690 total inpatient and outpatient operating room hours (Table 7) reported to VHI for 2017, divided by 52,165 total inpatient and outpatient operating room visits reported to VHI for that same year (Table 5);

Table 7: PD 5 Total OR Room Hours: 2017

Acute Care Hospital	Inpatient OR Hours	Outpatient OR Hours	Total Hours
Carilion Roanoke Community Hospital	3	3,854	3,857
Carilion Roanoke Memorial Hospital	32,988	22,483	55,471
LewisGale Hospital - Alleghany	483	1,180	1,663
LewisGale Medical Center	9,384	11,399	20,783
TOTAL	42,858	38,916	81,774
Outpatient Surgical Hospital			
Blue Ridge Surgery Center	0	5,067	5,067
Fairlawn Surgery Center, LLC	0	2,347	2,347
Roanoke Ambulatory Surgical Center	0	7,644	7,644
Roanoke Valley Center for Sight	0	3,858	3,858
TOTAL	0	18,916	18,916
Grand Total	42,858	57,832	100,690

Source: VHI 2017 Data

AHORV = 1.9302

$$FOR = ((ORV/POP) \times (PROPOP)) \times AHORV$$

$$1600$$

 $FOR = 102,872.53 \div 1,600$

FOR = 64.29 (65) General Purpose Operating Rooms Needed In PD 5 in 2024

Using the above methodologies, the conclusion would be logically reached that there will be a need for one additional GPOR in PD 5 by the year 2024. The proposed project, which merely seeks to expand the scope of a limited use OR to include ENT surgeries, is inventory neutral and would not affect the operating room inventory of PD 5.

B. Projects involving the relocation of existing operating rooms within a health planning district may be authorized when it can be reasonably documented that such relocation will: (i) improve the distribution of surgical services within a health planning district; (ii) result in the provision of the same surgical services at a lower cost to surgical patients in the health planning district; or (iii) optimize the number of operations in the health planning district that are performed on an outpatient basis.

As the proposed project merely seeks to expand a limited use ophthalmic OR to include ENT, relocation of existing operating rooms within the health planning district is not necessary to effectuate the proposed project.

12VAC5-230-510. Staffing.

Surgical services should be under the direction or supervision of one or more qualified physicians.

The applicant has provided assurances that surgical services will be under the direction and supervision of one or more qualified physicians.

Required Considerations Continued

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.

The applicant proposes to expand the use of their limited use OR by adding ENT surgeries. While the operating room will remain limited to ophthalmic, ENT, and oculofacial plastic surgical procedures, approval of the project would likely foster some degree of institutional competition with other outpatient surgical hospitals that perform ENT procedures in the area to some degree. However, as RVCS has not provided evidence showing the expected volume of the ENT surgeries that would occur should the proposed project be approved, and the degree to which Dr. Lenkowski utilizes his available OR time at BRSC, it is unclear if approval of the project would materially increase beneficial competition in the area.

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.

The proposed project is unlikely to have a detrimental effect on the utilization of existing health systems. Of the many issues raised by BRSC in opposition to the project, none related to the effect the proposed project would have on their business or the utilization of the GPORs at their facility. Moreover, the time allotted to Dr. Lenkowski at BRSC, an eight

hour block on Wednesdays, only 67% of which is used according to BRSC, does not represent a large portion of BRSC's total OR time. As such, DCOPN concludes that it is unlikely that approval of the proposed project would have a detrimental effect on the utilization at BRSC.

6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital.

As demonstrated by Table 2, the total capital cost of this proposed project is estimated to be \$25,620 and would be funded through the internal resources of RVCS. The costs of this project, which are limited solely to additional equipment to be added to the ophthalmic operating room that are necessary to perform ENT surgery, are minimal and reasonable. The applicant asserts that no additional staff will need to be hired as part of the proposed project. While the project is inexpensive, the applicant does not raise any benefits to the project outside of those previously discussed unsupported claims that DCOPN finds too speculative to adopt.

7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services. (ii) The potential for provision of services on an outpatient basis. (iii) Any cooperative efforts to meet regional health care needs. (iv) At the discretion of the Commissioner, any other factors as may be appropriate.

The proposed project would not provide improvements or innovations in the financing and delivery of health services, as demonstrated by the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served. (i) The unique research, training, and clinical mission of the teaching hospital or medical school. (ii) Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. The applicant is not a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Findings and Conclusions

DCOPN finds that the proposed project to expand the scope of surgery services to permit ENT surgery at RVCS' Roanoke facility is inconsistent with the applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia.

Furthermore, the status quo is a viable alternative to the proposed project. While the proposed project is consistent with the SMFP, the applicant has failed to raise any substantive arguments that the proposed project would offer any benefit to the public under the remaining seven Required Considerations. Finally, DCOPN finds that the total capital cost of this proposed project is estimated to be \$25,620. The costs are minimal and reasonable and would be funded through the internal resources of RVCS.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends denial of the proposed project to expand the scope of surgical services at Roanoke Valley Center for Sight to permit ENT surgery at their Roanoke facility for the following reasons:

- 1. The project is inconsistent with the applicable criteria and standards of the State Medical Facilities Plan and the eight Required Considerations of the Code of Virginia.
- 2. The applicant did not raise any substantive arguments that the proposed project would offer any benefit to the public under the Required Considerations.
- 3. The status quo is a viable alternative to the proposed project.